NEWS RELEASE

Veritas In Silico

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Company Name: Veritas In Silico Inc.
Representative: Shingo NAKAMURA,
Representative Director and CEO
Listed on: TSE Growth
Stock Ticker Code: 130A
Contact Person: Tsuneo GODA,
Executive Officer, General Manager,
Corporate Planning Division
Email: ir@veritasinsilico.com

Pre-Consultation Meeting with Pharmaceuticals and Medical Devices Agency (PMDA) towards the Commercialization of the Drug Delivery System "Perfusio"

Veritas In Silico Inc. (hereinafter referred to as "the Company"), leveraging its AI drug discovery platform "aibVIS," is dedicated to the research and development of mRNA-targeted small molecule drugs and nucleic acid drugs, which form its core business. In addition to these efforts, the Company has developed a novel Drug Delivery System[*1] (hereinafter referred to as "DDS"; product name "Perfusio"), applicable to various pharmaceuticals, including nucleic acid drugs. As announced in our press release dated December 15, 2025, titled "Completion of Patent Examination and Patent Grant Procedures for Drug Delivery System "Perfusio"" the patent registration for this system has been successfully completed.

On January 1, 2026, the Company established Corporate Venture Office and is actively progressing towards the commercialization of "Perfusio," aiming for its launch during its mid-term business plan (FY2026-2027).

The Company is pleased to announce that it has initiated pre- Consultation Meeting with the Pharmaceuticals and Medical Devices Agency (PMDA)*[2], a crucial step towards obtaining the necessary medical device approval for the commercialization of Perfusio.

"Perfusio" functions by positioning catheters in both the venous and arterial sides of a target organ, thereby occluding the vessels and creating a state where the target organ is isolated from systemic circulation within the body. In this isolated state, drugs can be administered through one catheter and recovered through the other, ensuring precise delivery of the drug to the target organ while simultaneously preventing systemic drug exposure. This innovative method is characterized by not requiring chemical modifications to the drug for DDS and applicable to various organs.

Existing catheters do not include such drug administration and recovery uses. To clarify the regulatory process for adding new application to a combination of existing catheters, we initiated General Consultations with PMDA in March of this year. Based on the outcomes of these consultations, we commenced a preliminary meeting for pre-Consultation Meeting with PMDA on May 14.

Through this preliminary meeting, the Company has decided on a strategy to obtain approval for "Perfusio" as a general-purpose medical device with novel applications, without conducting new experiments for data acquisition. Moving forward, we will proceed to a formal pre-Consultation Meeting with PMDA, steadily advancing the necessary processes to secure approval for a targeted launch.

● Comment from Jun Sasaki, General Manager of Corporate Venture Office

Since commercialization of 'Perfusio' as our new business since January this year. The recent meetings with PMDA clearly demonstrates the smooth progress of this initiative. The greatest strength of 'Perfusio' lies not only in its ability to directly administer drugs to the target organ but also in its capability to recover them after administration, representing an unprecedented clinical innovation.

In parallel to obtain approval of ‘Perfusio’, we are also advancing partnerships with companies specializing in catheter businesses. We are expecting to collaborate with these companies as partner and expand the applications of their existing catheters and contribute to their sales growth.

Furthermore, we are confident that 'Perfusio' is highly versatile and applicable to a wide range of pharmaceuticals. Given its high potential to avoid systemic toxicity, that compounds for which systemic toxicity was observed in Phase I clinical trials could return to the regulatory development process by switching to 'Perfusio'-based administration and recovery clinical trials, thus preventing development discontinuation.

Beyond its application in our own pipeline development, we will propose licensing 'Perfusio' to pharmaceutical companies as a means to restart suspended development projects. Through this, we aim to deliver new medicines to society more quickly and address unmet medical needs.

● Glossary for Reference

*1 Drug Delivery System (DDS): A system designed to deliver the active pharmaceutical ingredient to a specific target (primarily an organ) for treatment. Traditionally, methods involve chemically attaching molecules to the drug to selectively reach the target organ, or encapsulating the drug in a lipid bilayer. However, our unique approach physically delivers the drug by accessing the target organ via both arterial and venous catheters, thereby qualifying it as a type of drug delivery system.

*2 Pharmaceuticals and Medical Devices Agency (PMDA): An independent administrative institution responsible for ensuring the efficacy, safety, and quality of pharmaceuticals and medical devices.

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For Further Information, Contact:
● Veritas In Silico Website Inquiry Form : https://www.veritasinsilico.com/en/contact/